

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

I. Status of the Claims

Claims 3-5, 10-11, 13 and 15 have been amended, and claim 14 has been cancelled. Meanwhile, claims 16-17 have been added. Support for these new claims can be found be found for example in original claims 10 and 15. Upon entry of these amendments, claims 1-13 and 15-17 will be pending.

II. Objections to the Specification

Applicant acknowledges the withdrawal of the prior objections to the specification.

The examiner newly objects to the specification for allegedly reciting the term “1.500 instead of 1500.” Applicant notes, however, that the term “1.500” was amended on July 8, 2008 to recite “1,500”. Nevertheless, applicant has adopted the examiner’s proposed term and believes, therefore, that the objection has been obviated.

III. Claim Objections

The examiner objects to claim 14 for reciting the “2-3500 l/min”. Applicant has cancelled the claim, rendering the rejection moot.

IV. Rejections Under 35 U.S.C. § 112

Applicant acknowledges the withdrawal of the prior rejections under § 112.

The examiner newly rejects claims 3-5, 10-11, 13 and 15 for alleged indefiniteness under § 112, ¶ 2 for reciting both narrow and broad ranges and for using the term “such as”. Applicant has amended the claims such that each claim recites a single range and deleted the term “such as”. Applicant believes, therefore, that the amendments obviate the rejection.

V. Rejections Under 35 U.S.C. § 103

The examiner rejects claims 1-2 and 5-15 over Lihme *et al.* as evidenced by “the molecular weight of IgG.” According to the examiner, Lihme teaches a method of purifying lactoperoxidase (LP) by applying to an expanded bed adsorption column a volume of bio-molecule-containing fluid having a temperature of 50°C, thereby “meeting all limitations of instant Claim 1 except the flow rate of at least 1500 cm/hour.” Office Action, pg. 6-7.

As to this missing element, the examiner asserts that “it would have been obvious ... to modify [Lihme’s] Expanded Bed Adsorption (EBA) column and/or process...so that said method applies a higher flow rate” allegedly because Lihme suggests that EBA columns are “more efficient and cost effective”. *Id.* at pg. 8. This inference overlooks Lihme’s clear teachings to the contrary, however.

The examiner cites to an example of Lihme’s that investigated the effect of varying the temperature during the loading of whey on the yield and purity of lactoperoxidase (LP) and lactoferrin (LF) at a linear flow rate of 7.5 cm/min (450 cm/hr). *See* WO 02/096215, Example 11. Lihme’s data show a decrease in LP yield when the loading temperature was raised from 4°C to 22°C, whereas LF yield increased. Conversely, LP yield increased when the loading temperature was raised from 22°C to 50°C, while LF yield decreased. It is unclear from Lihme’s disclosure, therefore, what advantage may spring from elevating temperatures during the loading process.

Meanwhile, Lihme specifically taught that increasing the linear flow rate *reduced* purification yield. *Id.* at Example 9. In particular, Lihme examined the effect of various flow rates of loading on the yield and purity of lactoperoxidase (LP) and lactoferrin (LF). The results show a clear trend of reduced yield following increases in flow rate. Indeed, the reduction was substantial when a high flow rate was employed. For instance, the data show that increasing the flow rate from 7.5 cm/min to 25 cm/min resulted in yield losses of lactoperoxidase and lactoferrin of 34% and 23%, respectively.

On one hand, therefore, Lihme taught that elevated temperatures during the loading process produces mixed results and that elevated flow rates significantly reduces purification

yield. On the other hand, nothing in Lihme suggested isolating bio-molecules via a combination of high temperature (*i.e.*, at least 40°C) and high flow rate (*i.e.*, at least 1,500 cm/hr). To the contrary, Lihme's failures using a high flow rate would have lead an artisan away from such a combination; this, notwithstanding the examiner's assertion that Lihme suggested that EBA columns are "more efficient and cost effective" than other chromatographic techniques.

For "the molecular weight of IgG," moreover, the examiner's invocation of "Immunoglobulin," an otherwise unidentified source with an unknown art-effective date, fails to cure the deficiencies of the primary reference. Accordingly, the examiner's combination of references does not evidence, as Section 103 requires, a reason to have combined the selected portions of the cited references, thereby to produce the claimed invention. Since it necessarily follows that a *prima facie* case of obviousness has not been established, applicant respectfully requests that the rejection be withdrawn.

The examiner also rejects claims 1-15 over Lihme *et al.*, as evidenced by "the molecular weight of IgG," in further view of Olander *et al.* Applicant respectfully traverses the rejection.

Lihme and "the molecular weight of IgG" are discussed above. Olander, cited for teaching "an industrial scale EBA column having 265 liters of adsorbent and having a diameter of 1.5 meter," fails to cure the deficiencies of the primary references. Pursuant to the rationale set out above, therefore, the examiner has not made out a *prima facie* case of obviousness. Applicant therefore requests withdrawal of the rejection.

Applicant submits that the application is in condition for allowance, and an early indication to this effect is requested. Examiner Kim is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account

No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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